Morgan Lewis

RECENT PART D CHANGES – IMPLICATIONS FOR PHARMACEUTICAL MANUFACTURERS
FX CONFERENCES

September 12, 2012

- Andrew Ruskin
- Partner
- Morgan Lewis
- Washington, DC
- 202.739.5960

aruskin@morganlewis.com

Part D Fundamentals

- Part D plan perspective.
  - Offer a voluntary pharmacy benefit package to Medicare beneficiaries.
    - Benchmark “standard” benefit structure, or actuarial equivalent.
    - Formulary used to control drug costs.

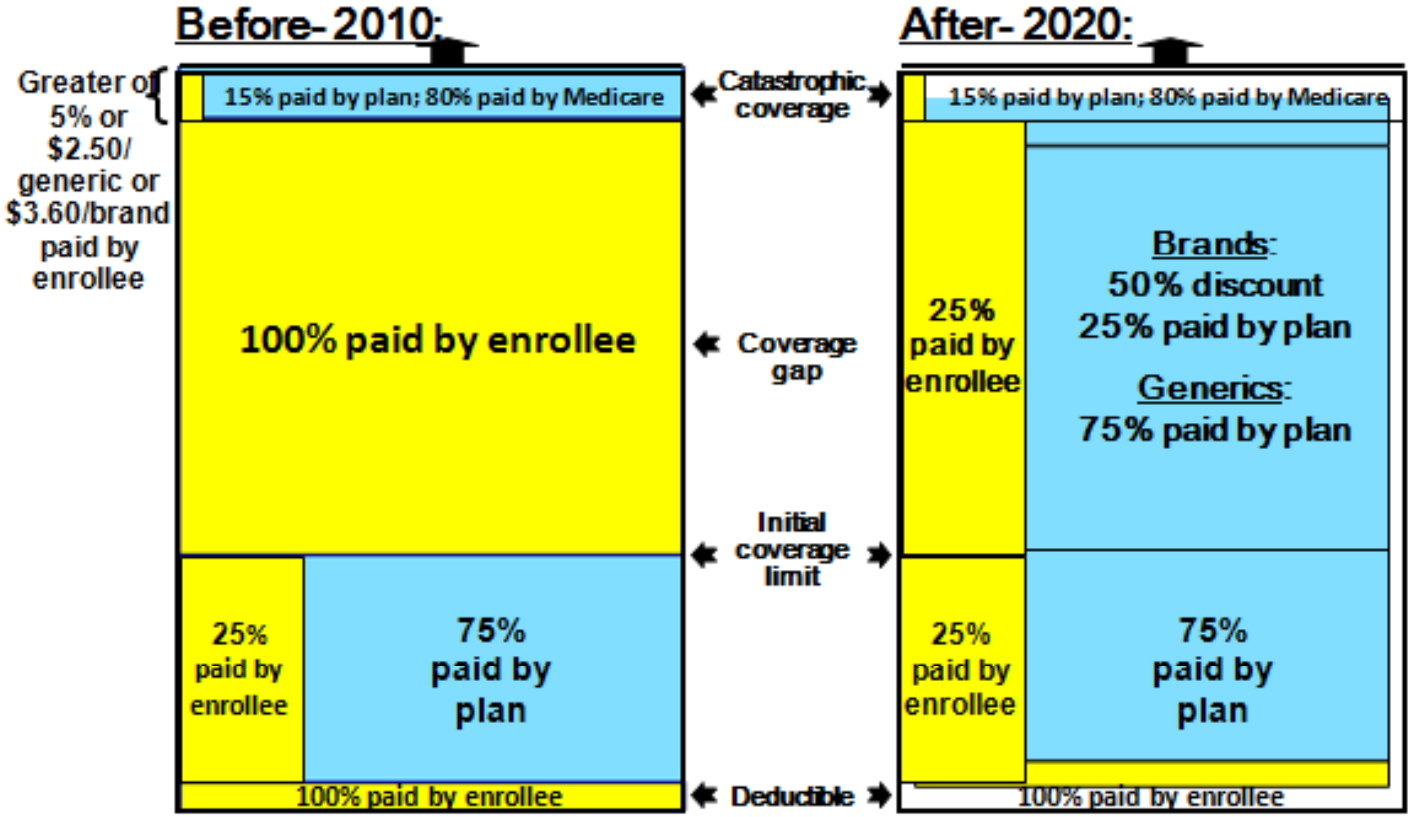
Part D Fundamentals (cont'd)

- Receive payment from CMS
  - Capitated amount based on bid average.
    - Adjusted for case mix
  - Reinsurance amount
  - LIS
  - Risk corridor payments
- Contract with pharmacies and manufacturers

Part D Fundamentals (cont'd)

- Beneficiary perspective

Standard Medicare Prescription Drug Benefit, *Before and After Health Care Reform*



SOURCE: Kaiser Family Foundation illustration of standard Medicare drug benefit in 2020 under the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act of 2010.

Closing the "Donut Hole"

Year	Branded, Biologic, Authorized Generic Coinsurance*	Generic Coinsurance
2010	100%	100%
2011	50%	93%
2012	50%	86%
2013	47.5%	79%
2014	47.5%	72%
2015	45%	65%
2016	45%	58%
2017	40%	51%
2018	35%	44%
2019	30%	37%
2020	25%	25%

- *Represents combination of 50% Manufacturer Discount under CGDP and CMS "direct" federal subsidy contribution to reduce cost sharing to level shown

Part D Fundamentals (cont'd)

- Manufacturer perspective
  - Part D drug definition
    - Medically accepted indication
    - FDA-approved prescription drug
    - Payment not be available under Medicare Part A or Part B
    - No statutory exclusion

Part D Fundamentals (cont'd)

- Covered by Part D PDP
  - Must structure formulary that does not discriminate against particular beneficiaries
    - » USP Model Guidelines as safe harbor
  - Must cover at least 2 drugs per class or category
  - Must be approved by P&T Committee

Part D Fundamentals (cont'd)

- Drugs within "protected classes" must all be covered, unless subject to an exception. Currently, the protected classes are:
  - Anticonvulsants
  - antidepressants
  - Antineoplastics
  - Antipsychotics
  - Antiretrovirals
  - immunosuppressants for the treatment of transplant rejection

Part D Fundamentals (cont'd)

- Rebates excluded from Medicaid Drug Rebate Program best price
- Coverage Gap Discount Program

Recent Rulemaking

- Final Rule published on April 12 (77 Fed. Reg. 22072)
- Purposes include:
  - Implement statutory provisions
  - strengthen beneficiary protections
  - exclude plan participants that perform poorly
  - improve program efficiencies
  - clarify program requirements

Recent Rulemaking (cont'd)

- Medicare Part D Coverage Gap Discount Program

Coverage Gap Discount Program

- The Affordable Care Act mandates that manufacturers of Branded Drugs, Biologics and Authorized Generics provide Part D enrollees 50% discounts of the "negotiated price" of such drugs dispensed in the Coverage Gap ("Donut Hole") in order for such drugs to be covered under Medicare Part D
  - Based on "negotiated price," without dispensing fees and vaccine administrative fees

Coverage Gap Discount Program (cont'd)

- Does not apply to Low Income Subsidy Beneficiary utilization, whose Donut Hole costs are paid by CMS
- Paid after a Part D Plan's supplemental benefits
- CMS can waive this requirement in its discretion

Coverage Gap Discount Program (cont'd)

- By January 30 for the next plan year
  - Submit contact information, labeler codes and ownership information
  - Submit signed manufacturer agreement with CMS
  - Submit signed third party administrator ("TPA") agreement
- Must add new labeler codes within 3 days of FDA assignment

Coverage Gap Discount Program (cont'd)

- A TPA is contracted with CMS to administer the program
  - TPA is the technical contact, responsible for invoicing manufacturers
  - TPA is Palmetto GBA
- TPA will issue claims-detail report and invoices that will be sent to manufacturers

Coverage Gap Discount Program (cont'd)

- CMS provides monthly prospective estimated payments of Coverage Gap Discounts to Part D plan sponsors, subject to annual reconciliation
- Part D plan sponsors adjudicate claim and administer discount at point of sale when enrollee is in Coverage Gap
- Part D plan sponsors provide prescription drug event ("PDE") claims data to CMS, including data on discounts provided
  - PDEs are supposed to be submitted monthly but can be filed/changed following the end of each plan year and even after the annual reconciliation

Coverage Gap Discount Program (cont'd)

- PDE is used by the TPA to invoice manufacturers for Coverage Gap Discounts
  - The TPA may invoice a manufacturer for a Coverage Gap Discount up to three (3) years from the date the drug was dispensed
- Manufacturers are electronically invoiced quarterly for Coverage Gap Discounts by the TPA, at 11-digit NDC level
  - Limited claims level data is provided

Coverage Gap Discount Program (cont'd)

- Exhibit C of the Manufacturer Agreement with CMS restricts the use of claims-level data

- "The Manufacturer may not use the Discount Information to perform functions not governed by this Agreement, including but not limited to non-Coverage Gap Discount payments to Part D sponsors and their subcontractors, payments to other provides of health and drug benefits under any Federal health care program and marketing activities."

Coverage Gap Discount Program (cont'd)

- Permitted use- financial statement forecasting and accounting purposes
- Must have administrative, technical, and physical safeguards

Coverage Gap Discount Program (cont'd)

- 10 year record retention period.
  - From any payment date
  - information includes
    - Manufacturer labeler codes
    - FDA drug approvals
    - FDA NDC Directory listings
    - NDC last lot expiration dates
    - Utilization and pricing information relied on by the manufacturer in disputes.

Dispute Resolution Process

- Timeline
  - Invoices arrive 30 days after each quarter end, except June, which arrive 60 days after quarter end.
  - Payments must be made via EFT 39 days later (including the one day that it takes to receive message electronically).
  - Manufacturers that fail to timely pay their invoices, even by a day, must pay the amount otherwise due plus an additional 25% of such amount.

Dispute Resolution Process (cont'd)

- Data items
  - Date of Service
  - Service Provider Identifier (NPI, UPIN)
  - Prescription/Service Reference Number
  - Product/Service Identifier (11-digit NDC)
  - Quantity Dispensed
  - Days Supply
  - Fill Number
  - Reported Gap Discount

Dispute Resolution Process (cont'd)

- Disputes should be made within 60 days of receipt of information.
- Types of Challenges.
  - Duplicate Invoice Item
  - Closed Pharmacy
  - Not PART D Covered Drug
  - Excessive Quantity
  - Invalid Days Supply
  - High Price of the Drug
  - Last Lot Expiration Date
  - Early Fill

Dispute Resolution Process (cont'd)

- Marketing Category is not NDA or BLA
- Date of Service prior to 01/01/2011
- PDE improperly invoiced beyond Manufacturer Agreement Invoice period
- Invalid Prescription Service Reference Number
- Gap discount for disputed PDE exceeds maximum discount amount for a single PDE
- Total accumulated gap discounts reported across multiple PDEs for a single beneficiary exceed cumulative maximum discount amount
- Other

Dispute Resolution Process (cont'd)

- Other Potential Challenges
  - Inconsistencies with historical trends.
  - NPI number inconsistent with type of authorized supplier (such as a SP product).
  - Utilization data inconsistent with other reports received from Part D Plan.

Dispute Resolution Process (cont'd)

- Launching a Dispute
  - Requires written notice of the issue or dispute to the TPA within 60 days of receipt of invoice.
    - Must be accompanied by supporting evidence.
    - Questions as to what documentation can be used, e.g., what about rebate reports from the Part D Plan? How about REMS data?

Dispute Resolution Process (cont'd)

- Dispute Resolution Process
  - Manufacturer and TPA use best efforts to resolve the dispute within 60 calendar days of receipt of such notification.
  - If not resolved, manufacturer may request CMS to provide for an independent review and determination.
    - Request must be made by the earlier of: (i) 30 days from the date of an adverse determination; or (ii) 60 days from the date of CMS' receipt of notice of the dispute if the manufacturer and TPA fail to reach resolution within 60 days.

Dispute Resolution Process (cont'd)

  - CMS chooses entity.
  - Choice is made within 90 calendar days of receipt of review request by the Manufacturer for such a review.

- Upon an unfavorable decision, manufacturer may request CMS Administrator review.
  - Must make request within 30 calendar days of receipt of notification of such determination.
  - CMS Administrator decision is final and binding.
  - **No judicial review.**

Dispute Resolution Process (cont'd)

- Audit Rights
  - Manufacturer can audit TPA's data annually.
  - Audit commenced on 60 days notice. Must include:
    - Reasonable basis for the audit; and
    - Description of the information required for the audit.
  - Review limited to a "statistically significant sample size of PDEs."
    - No audit of CMS records.
    - Records are confidential and reviewed on-site.

Dispute Resolution Process (cont'd)

- Data elements subject to audit are:
  - Contract Number
  - Plan Benefit Package Identifier
  - Ingredient Cost Paid
  - Dispensing Fee Paid
  - Total Amount Attributed to Sales Tax
  - Low-Income Cost Sharing Amount
  - Non-covered Plan Paid Amount
  - Vaccine Administration Fee
  - Total Gross Covered Drug Cost Accumulator
  - True Out-of-Pocket Accumulator

Dispute Resolution Process (cont'd)

- Tips for Preparing for Dispute Resolution Process
  - Develop policies/screens.
  - Docket appeal due dates.
  - Secure data that can be used to impugn reports.
  - Make sure that all of the relevant documentation is included at the initial level, and be very clear in any cover letter as to how the documents prove the manufacturer's contention.
  - Understand and follow TPA rules.
  - Time exercise of audit right to maximize chances of success during appeal.

Negotiating with Part D Plans

- Can seek to carve out double rebates, but Part D Plans not required to acquiesce.
- At a minimum, need to have a rebate reductions clause limiting cumulative rebate to WAC.
- Seek to have amounts used to lower “negotiated price,” but economic disincentive for Part D Plan.

Negotiating with Part D Plans (cont'd)

- No impact on formulary placement.
- Consider a clause requiring Part D Plan cooperation in gathering information that could be useful in a dispute (subject to HIPAA limitations).
- Consider whether it is even more important to bifurcate rebate negotiations for commercial and Part D.

Bona Fide Service Fees

- Bona fide service fees
  - Bona fide service fees means fees paid by a manufacturer to an entity that represent fair market value for a bona fide, itemized service actually performed on behalf of the manufacturer that the manufacturer would otherwise perform (or contract for) in the absence of the service arrangement, and that are not passed on in whole or in part to a client or customer of an entity, whether or not the entity takes title to the drug.

Bona Fide Service Fees

- FMV
- Itemized service
- Actually performed on behalf of manufacturer
- Manufacturer would otherwise have performed for itself
- Fees not passed along to client or customer

Bon Fide Service Fees (cont.)

- Admin fees not considered price concessions, meaning that does not reduce reimbursable costs
- Manufacturers must accurately describe admin fees as price concessions or bona fide service fees.
  - United States of America ex rel Streck v. Allergan Inc., --- F.Supp.2d ----, 2012 WL 2593791 (E.D.Pa.) (July 3, 2012).